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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,121	11.06.2000	Brian Mathur	LEX-0083-USA	8244

24231 7590 12/13/2001

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/13/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/707,121

Applicant(s)

MATHUR ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

The amendment filed on October 17, 2001, amending claims 1-3 and adding claim 4, has been entered.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 101***

Newly submitted claim 4 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claim 4 is drawn to polynucleotides encoding proteins of unidentified function. The claimed polynucleotides are not supported by either a specific and substantial asserted utility. The specification fails to provide objective evidence of any activity for the encoded proteins or to show that these proteins even exist. Applicant only states that the encoded protein sequence shares structural similarity with animal kinases, especially serine/threonine protein kinases (page 2, lines 2-5). Since the specification sets forth no specific function for the encoded protein, the claimed polynucleotides encode a protein with no ascribe function. No specific, substantial and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material is indicated. Identifying a polynucleotide as encoding a kinase-like protein does not endow the polynucleotide with such a utility. Therefore,

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there is no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding a kinase.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. In the state of the art, the function of a polynucleotide is unpredictable from its structure and the functionality of a polynucleotide must be known in order to use the polynucleotide. Therefore, the specification does not teach how to use polynucleotides with unknown function.

### ***Response to Arguments***

Applicant's arguments filed October 17, 2001 have been fully considered but they are not persuasive.

Claims 1-3 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Applicants argue that novel human kinase and fragments of human kinases have utility (Remarks page 4 through 6) and that page 8 of the specification provides a detailed description of the utility of the claim DNA sequences (Remarks, page 5, 3<sup>rd</sup> paragraph). The examiner disagrees. The rejection was based on the utility of the particular sequence of SEQ ID NO:1 and not the whole genus of novel human kinases or newly identified genomic sequences. Identifying a polynucleotide as encoding a kinase-like protein does not endow the polynucleotide with such a utility. The specification fails to provide objective evidence of any activity for the encoded proteins or to show that these proteins even exist. Applicant only states that the encoded protein sequence shares structural similarity with animal kinases, especially serine/threonine protein kinases (page 2, lines 2-5). Since the specification sets forth no specific function for the encoded protein, the claimed polynucleotides encode a protein with no ascribed function. Therefore, there is no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding a kinase.

***Claim Rejections - 35 USC § 112***

Claims 1-3 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that claim 1 has been amended to identify the function of the fragments as encoding novel human kinases (Remarks, page 8, 1<sup>st</sup> paragraph). The examiner disagrees. Claim 1 is still drawn to DNA fragments encoding polypeptides of unknown activity, or inactive variants with an unlimited structure.

Since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. In the state of the art, the function of a polynucleotide is unpredictable from its structure and the functionality of a polynucleotide must be known in order to use the polynucleotide. Therefore, the specification does not teach how to use polynucleotides with unknown function.

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that claim 1 has been amended to identify the function of the fragments as encoding novel human kinases (Remarks, page 8, 1<sup>st</sup> paragraph). The examiner disagrees. Claim 1 is still drawn to DNA fragments encoding polypeptides of unknown activity, or inactive variants with an unlimited structure.

Claim 1 is drawn to DNA molecules comprising 454 contiguous bases of a novel human kinase polynucleotide (SEQ ID NO:1) encoding polypeptides with of unknown activity, or inactive variants with no limitation on structure. A description of about 17% of

the whole structure of SEQ ID NO:1 amounts to an insufficient description of the structure of the DNA molecule in this claim. The specification also does not describe the function of all the polypeptide sequences encoded by the polynucleotides derived or modified from SEQ ID NO:1 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims.

Claim 2 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 2 to specify highly stringent condition. However the exact hybridization condition is unclear because the highly stringent condition defined on page 4, lines 17-29 is one description of a highly stringent condition. Different nucleic acids hybridize to a DNA sequence under different conditions. Therefore, the scope of DNA molecules in claim 2 is unclear.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

December 6, 2001

  
PONNATHAPURA ACHUTAMURTHY  
SUPERVISOR